



Gavin Spencer
Chief Executive Officer

Shareholder Letter

Topline results from the Denali Phase 3 clinical trial for our lead program, NCX 470 in glaucoma

Dear Shareholder,

The results are in! After tremendous work by the Nicox, our trial sites and partner teams, spanning COVID disruption and one of the most difficult financing periods for biotech companies, we now have the topline results from the Denali Phase 3 clinical trial for our lead program, NCX 470 in glaucoma.

The efficacy and safety results have validated NCX 470's therapeutic profile, replicating the performance seen in the first Phase 3 trial, Mont Blanc. In doing so, we have met the established efficacy requirements for filing New Drug Applications (NDA) in both the U.S. and China.

This means our story continues with new chapters ahead. Marketing approvals for NCX 470, expected from 2027 onwards, would lead to recurrent revenue and future milestones, continuing for potentially 10 to 15 years.

Key activities to support the future commercialization of NCX 470 in the short-term are:

- Finalizing the remaining data, such as supportive pharmacokinetic studies and pharmaceutical development studies required to submit NCX 470 for approval
- Writing of the NDA
- Branding development for NCX 470
- Preparation for commercial launch

The Nicox contribution to these activities will be led by our development and alliance management teams, working closely with both Kowa and Ocumension, for the U.S. and China respectively. All costs for filing the NDAs and commercializing NCX 470 are the responsibilities of Kowa and Ocumension in their respective licensed territories.

...and after?

The Kowa partnership announced in July this year gives us a springboard for the future of our company. With the completion of Denali, together with our partnerships, we have demonstrated that Nicox can deliver on both the development of major clinical assets and the associated financing, whilst simultaneously implementing commercial solutions that add value. We are considering strategic options that access new opportunities to optimize the use of this experienced team and maximize the future value of NCX 470.

Our NCX 470 licensing deals

NCX 470 is now globally licensed in partnerships with two top-tier pharmaceutical companies, Kowa and Ocumension Therapeutics.

As mentioned above, based on submitting applications to market NCX 470 in 2026 in the U.S. and China, we expect to start receiving recurrent royalty revenue from 2027 in those territories. In the years to come, this will extend to Japan, where a Phase 3 program is ongoing, as well as in other territories that can accept the packages used for U.S. approval.

With the Denali results, the Kowa deal milestone value is potentially up to €127 million, of which we have received €12.5 million. The next development milestones will be received on the submission then approval in the U.S., followed by royalties and subsequently, commercial sales milestones.

Financing

The payments associated with the July Kowa licensing deal – the €7.5 million upfront and the €5 million payment now due on the announcement of the Denali Phase 3 clinical data – have allowed us to significantly reduce the Company's debt, and extend the cash runway. This has been supplemented by the expanded financing with Vester Finance. We will provide a full update on our financial position shortly.

Staying in touch and answering your questions

As a result of shareholder questions, we recently added a document explaining the June 2024 warrants: [Nicox June 2024 Warrant Q&A](#). As we see other topics that could be of interest or of use to many of our shareholders, we will continue to provide explanations through appropriate means.

If you have a question, please address it in the first instance to us at communications@nicox.com. E-mail is our preferred route for shareholder contacts, so we suggest you use this if you can. You can also send your message via the website: [General Enquiries - Nicox](#), or leave a vocal message on +33 (0)4 97 24 53 00. If you call us, please ensure you leave your contact details.

We are more than happy to answer your questions regarding the Company and our development programs. As a reminder, we maintain an up-to-date corporate presentation on the website: [Corporate Presentation](#).

I thank you once again for your continued support as a shareholder, particularly since the beginning of 2024, and look forward to updating you on the future of Nicox now that we have demonstrated and unlocked the value of NCX 470.

Yours sincerely,

Gavin Spencer
Chief Executive Officer